ATTACHMENT D

SUMMARY OF SAFETY AND EFFECTIVENESS

Cardinal Health 303, Inc.

Alaris® PC Unit

Models 8000 and 8015

JUL - 9 2009

SUBMITTER'S NAME: **Cardinal Health 303, Inc.**

10020 Pacific Mesa Blvd.
San Diego, CA 92121
(858) 617-5925
(858) 617-5977 FAX

CONTACT PERSON: **Michelle J. Badal, RAC**
Vice President, Regulatory Affairs

DATE PREPARED: May 1, 2009

DEVICE NAME: **Proprietary Name:** Alaris® PC Unit
Common Name: Infusion Pump
Classification Name: Pump, Infusion, FRN (880.5725)

PREDICATE DEVICE: Alaris® PC Unit (K051641, October 20, 2005)

DEVICE DESCRIPTION

The Alaris® System is a modular system that consists of a point-of-care unit (PC Unit) that provides the main user interface and power supply for the associated infusion and monitoring modules. The enhanced PC Unit will include a faster processor, increased memory, and a color screen. This update is only for the Alaris® PC Unit and does not require any change to the associated modules, systems, or accessories of the Alaris® System.

SUMMARY OF SAFETY AND EFFECTIVENESS
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SUBSTANTIAL EQUIVALENCE

With the exception of the device modification presented in this submission, the Alaris® PC Unit is essentially the same as the originally submitted predicate device. The intended use, principles of operation, fundamental scientific technology, method of manufacture, and application are essentially the same.

INTENDED USE

The intended use of this device has not changed from the original submissions in terms of content or intent:

The Alaris® PC Unit is the main user interface unit and power supply of the Alaris® System, a modular system to be used with Alaris® System modules (aka Medley™ System modules) intended for use in today's growing professional healthcare environment for facilities that utilize infusion and/or monitoring devices. The specific intended use for each Alaris® System module is specified in its respective submission

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Alaris® PC Unit and the predicate devices has been performed. The results of this comparison demonstrate that the modified Alaris® PC Unit is equivalent in technological characteristics to the unmodified device and that the fundamental scientific technology of the predicate device has not been altered.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2009

Ms. Michelle J. Badal
Vice President Regulatory Affairs
Cardinal Health 303, Incorporated
10020 Pacific Mesa Boulevard
San Diego, California 92121

Re: K091308
Trade/Device Name: Alaris® PC Unit
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: June 26, 2009
Received: July 1, 2009

Dear Ms. Badal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment B

INDICATIONS FOR USE

510(k) Number (if known): K091308

Device Name: **Alaris® PC Unit**

Indications for Use:

The Alaris® PC Unit is the main user interface unit and power supply of the Alaris® System, a modular system to be used with Alaris® System modules (aka Medley™ System modules) intended for use in today's growing professional healthcare environment for facilities that utilize infusion and/or monitoring devices. The specific intended use for each Alaris® System module is specified in its respective submission.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091308